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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	9

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☑ Responsive to communication filed on _____ ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 12-19 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☑ Claims 1-11 and 20 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☑ Claims 12-19 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Claims 12-19 are pending in the applications, and claims 1-11 have been canceled.

Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that a search of the prior art which focuses on such PSA selectively cleavable oligopeptides would be comprehensive with respect to all of the instant inventions yet would not require a serious burden on the Examiner . As previously stated, applicants' election is acknowledged, but their arguments are moot in view of the cancellation of claims 1-7; therefore a response to the arguments are not necessary.

The requirement is still deemed proper and is therefore made FINAL.

The rejection of claims 1 and 5-6 under 35 USC 101 as claiming the same invention as that of co-pending application '092 has been withdrawn in view of the cancellation of claims 1-7.

The rejection of claim 1 under 35 USC 101 as claiming the same invention as that of co-pending application Serial Number 08/540412 has been withdrawn.

The rejection of claims 2-4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-4 of co-pending application '092 has been withdrawn.

The rejection of claims 1-6 under 35 USC 102(b) as being anticipated by Lilja et al J. Biological Chemistry reference has been withdrawn in view of applicants' cancellation of claims 1-6.

The rejection of claim 7 under 35 USC 103 as being unpatentable over Lilja et al reference has been withdrawn in view of the cancellation of claim 7.

The rejection of claims 12-19 under the judicially created doctrine of obviousness -type double patenting as being unpatentable over claims 20-23 of co-pending application for the same reason given in the office action mailed 02/03/97.

The rejection of claims 12-18 as being obvious over Lilja et al in view of Kaneko et al US Patent No. 5,3,49,066 has been maintained for reason set forth in the previous office action and will be discussed below.

Applicant's arguments filed May 5, 1997 have been fully considered but they are not persuasive.

With respect to claims 12- 18 as being obvious of Lilja et al in view of Kaneko et al , applicants' arguethat the reference of Lilja et al does not read on the oligopeptide portion of the peptides since semenogelin I and II are excluded. As previously stated in the prior office action, the use of term "comprises" renders semenogelin I or II protein inclusive of the claimed oligopeptide . Therefore a person of skill in the art can envisage semenogelin I and II when reading applicants' claim. The use of semenogelin I or II in conjugated form is also envisage as discussed below.

Applicants'invention also relates to an anti-cancer composition which comprises the oligo peptides of this invention covalently bonded directly or through a chemical linker to a cytotoxic agent. Applicants defines this combination as a conjugate (see spec pages 11-15). Applicants further disclose that the cytotoxic activity of the cytotoxic agent is reduced or absent when the

oligopeptide containing the PSA cleavage sit eis bonded directly or through a chemical linker to a cytotoxic agent and is intact. (see spec. P. 15, lines 15-19). They even further disclose that the cytotoxic activity of the cytotoxic agent increases significantly or returns to the activity of the unmodified cytotoxic agent upon proteolytic cleavage of the attached oligopeptide at the cleavage site.(see p. 15 lines 20-24). Semenogelin I or II is capable of being cleaved at various cleavage site, hence, the reason why applicants oligopeptide reads on said semenogelin I or II (see Lilja et al , Biolg. Chem, vol. 264, p 1897). Applicants also suggest that there are several points of cleavage where semenogelin is selectively proteolytically cleaved by free PSA. (see p. 4, lines 7-9). Because semenogelin I or II reads on applicants' oligopeptide, semenogelin I or II is also expected to have the inherent function of being capable of incorporation into therapeutic agents which comprise conjugates of such oligopeptides and known cytotoxic agent which are useful in the treatment of prostatic cancer.

Kaneko et al lists various cytotoxic regents that can comprise conjugates, including anthracyclines : adriamycin, daunomycin, detorubicin,etc(see col.10,lines 50-59). Kaneko further discloses that the cytotoxic reagents may be any molecule containing a carbonyl group; therefore the cytotoxic reagents are not just limited to the class of compounds which comprise the anthracyclines. In addition, Kaneko et al teach methods for delivering cytoxic reageants to target cells to treat diseases such as cancers and other tumors, non cytocidal viral or pathogenic infection(see Kaneko et al, col.9, lines 20-24). Therefore,one of ordinary skill in the art would have been motivated by the combination of references, Lilja et al and Kaneko et al to form

conjugates comprising semenogelin I or II bonded directly or via a chemical linker to a cytoxic reagent to treat prostatic cancer , wherein said cytotoxic reagent is delivered to target cell to treat said cancer .

Said Kaneko reference was merely applied because they attached cytotoxic agent, optionally via a chemical linker to a ligand not because they teach any particular conjugates per sa

Therefore the examiner contends that the combination of Lilja et al which teach proteins which can be cleaved by PSA antigen and the reference of Kaneko et al which teaches cytotoxic agents which can be linked to proteins, wherein the cytotoxic agents is delivered to target cells to treat diseases such as cancer renders applicants' invention obvious.

It is noted that applicants argue that applicant's invention exclude the protein taught by Lilja et al since applicants exclude these proteins in the body of their disclosure on page 9, lines 9-10 of the specification. As was discussed above, "comprises" makes the proteins inclusive,: however,if applicants wish to exclude such proteins such language should be incorpoarte into the claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Marshall whose telephone number is (703) 1030.

sgm
August 4, 1997

CECILIA J. TSANG
SUPERVISORY PATENT EXAMINER
GROUP 1800